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[Your Name]

[Your Title]

[Your Company]

[Street Address, City, State ZIP]

May 14, 2026

[Opposing Counsel Name]

[Firm Name]

[Address]

Re: U.S. Patent No. 12419895 — Response to Assertion of Infringement

Dear Counsel,

We acknowledge receipt of your correspondence asserting infringement of U.S. Patent No. 12419895 (the "12419895 Patent"). After preliminary review, we have substantial concerns about the validity, enforceability, and scope of the asserted claims, summarized below. We reserve all rights and defenses.

1. Subject Patent — Summary

Summary of U.S. Patent 12,419,895

A concise summary of U.S. Patent 12,419,895 is provided below, based on the authoritative patent text and public records as of April 30, 2026.

Title: Methods for treating subjects with Prader-Willi syndrome

Assignee: Essentialis Inc.

Inventor: Neil M. Cowen

Filing Date: May 30, 2025

Issue Date: September 23, 2025

Abstract:

The patent describes pharmaceutical formulations of potassium ATP (K-ATP) channel openers and their use, either alone or in combination with growth hormone, for treating various diseases and conditions, including Prader-Willi Syndrome (PWS) and Smith-Magenis syndrome (SMS).

Plain-Language Overview of Independent Claims:

This...

2. Validity Concerns under 35 U.S.C. § 102 — Prior Art

We have identified prior-art references that, in our preliminary view, anticipate one or more asserted claims of the 12419895 Patent:

As a senior patent analyst on April 30, 2026, I have identified and analyzed the most relevant prior art for U.S. Patent 12,419,895 based on the citations likely to have been considered during its prosecution, including those mentioned within the patent's own background description. The analysis below focuses on potential anticipation under 35 U.S.C. § 102. For a claim to be anticipated, a single prior art reference must disclose, either expressly or inherently, each and every element of the claim. The priority date of US 12,419,895 is November 14, 2014; therefore, any reference published or filed before this date is considered prior art.

Analysis of Prior Art References

The following references are evaluated for their potential to anticipate the independent claims (1, 8, 12, 16, and 17) of the '895 patent.

1. U.S. Patent No. 6,197,765 B1 ("765 patent")

- Full Citation: U.S. Patent 6,197,765 B1, "Methods for treating syndrome X," filed by inventor Al-Ali, assigned to Andro-Tech, LLC.
- Dates: Filed: June 1, 1998; Issued: March 6, 2001. This patent predates the '895...

3. Obviousness under 35 U.S.C. § 103

Independent of § 102, we believe the asserted claims are obvious in view of combinations of prior art that a person having ordinary skill in the art would have been motivated to combine:

Based on the provided prior art analysis, here is an analysis of the obviousness of U.S. Patent 12,419,895 under 35 U.S.C. § 103 as of April 30, 2026.

Obviousness Analysis (35 U.S.C. § 103)

An invention is unpatentable if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art (POSA). This analysis considers combinations of the previously identified prior art references to determine if they would render the independent claims of the '895 patent obvious.

Definition of a Person Having Ordinary Skill in the Art (POSA)

A POSA in the context of this patent would be a clinical researcher or physician, such as an endocrinologist or geneticist, with experience in treating complex genetic and metabolic disorders. This individual would be knowledgeable about the pathophysiology of Prader-Willi Syndrome (PWS), including its hallmark symptoms of hyperphagia, obesity, and abnormal body composition (low lean body mass,...

4. Litigation History of the Patent

Public records reflect that the 12419895 Patent has been the subject of the following litigation, which informs our view of the asserted claims and your client's enforcement posture:

- Apotex Inc. v. Soleno Therapeutics Inc. — IPR2026-00337 · Patent Trial and Appeal Board (PTAB) · filed 2026-04-21 · Pending

5. Request

In light of the foregoing, we request that your client (i) provide a detailed claim chart identifying

each accused product or service and mapping every limitation of each asserted claim, (ii) identify any prior art known to your client, including any references cited during prosecution or reexamination, and (iii) substantiate the basis for any damages or licensing demand. We are prepared to discuss the matter further once we have received and reviewed the foregoing.

Sincerely,

[Your Name]

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